James R. Condo (#005867)
SNELL & WILMER L.L.P.
One Arizona Center
400 E. Van Buren, Suite 1900
Phoenix, AZ 85004-2204
Telephone: (602) 382-6000
jcondo@swlaw.com

Richard B. North, Jr. (admitted *pro hac vice*)
Georgia Bar No. 545599
Matthew B. Lerner (admitted *pro hac vice*)
Georgia Bar No. 446986
NELSON MULLINS RILEY & SCARBOROUGH LLP
Atlantic Station
201 17th Street, NW, Suite 1700
Atlanta, GA 30363
Telephone: (404) 322-6000
richard.north@nelsonmullins.com
matthew.lerner@nelsonmullins.com

Attorneys for Defendants
C. R. Bard, Inc. and
Bard Peripheral Vascular, Inc.

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation, This Document Relates to: Lisa Hyde, et al. v. C. R. Bard, Inc., et al. CV-16-00893-PHX-DGC	No. 2:15-MD-02641-DGC **DEFENDANTS' TRIAL BRIEF** (Assigned to the Honorable David G. Campbell)

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

Plaintiffs have five remaining claims against Bard: strict liability design defect (Count III), negligent design (Count IV), negligence per se (Count IX), loss of consortium (Count XV), and punitive damages.[1] Bard submits this Trial Brief to address legal issues that may arise at trial concerning Plaintiffs' claims for design defect.

I. Background

Wisconsin dramatically transformed its product liability law in 2011 in what has been characterized by legislators, courts, and commentators as a "sea change." Before the change, one Wisconsin Supreme Court Justice described Wisconsin as a "'renegade' jurisdiction" due to its anachronistic adherence to the consumer expectations test to determine whether a product is defectively designed, notwithstanding the almost universal adoption of a negligence-based, risk/utility approach followed by most other states. *Horst v. Deere & Co.*, 769 N.W.2d 536, 557 (Wis. 2009) (Gableman, J., concurring).

The question of whether Wisconsin should jettison the consumer expectations test, based on Wisconsin's interpretation of the Restatement (Second) of Torts § 402A (hereinafter "§ 402A"), and adopt a negligence-based approach from the Restatement (Third) of Torts: Product Liability § 2(b) (hereinafter "§ 2(b)"), first came to head in 2001 in *Green v. Smith & Nephew*, 629 N.W.2d 727 (Wis. 2001). The majority reaffirmed Wisconsin's adherence to the consumer expectations test, but, in a dissent, former Supreme Court Justice Diane Sykes passionately advocated for the adoption of § 2(b).

Following *Green*, in 2005, the Wisconsin Legislature attempted to adopt legislation that included language that is almost verbatim § 2(b).[2] But, the then-Democratic Governor Jim Doyle vetoed the bill because the "bill makes sweeping changes to Wisconsin's product liability law and places a larger burden on consumers to prove the defective condition of products."[3] The issue emerged again in 2009 in two opinions: *Godoy ex rel.*

[1] Bard addresses Plaintiffs' claims for negligence per se, loss of consortium, and punitive damages in the Pretrial Order.

[2] *See* Wis. Sen. Bill 58 (LRB-1927) (passed November 9, 2005), attached as Tab 10 to the accompanying Notebook of Authorities ("NOA").

[3] *See* Ltr. from Gov. Jim Doyle to Wis. Sen. Members (January 6, 2006), NOA at Tab 11.

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

Gramling v. E.I. du Pont de Nemours & Co., 768 N.W.2d 674 (Wis. 2009) and *Horst*, 769 N.W.2d 536. Although neither case adopted § 2(b)—instead clinging to the consumer expectations test—both cases included vigorous concurring opinions advocating for adoption of § 2(b), and vigorous (and sometimes impassioned) concurring (in *Godoy*) and dissenting (in *Horst*) opinions against adoption of § 2(b).

In November 2010, Wisconsin elected Republican Scott Walker as Governor. During his inauguration speech on January 3, 2011, Governor Walker declared that "Wisconsin is open for business" and immediately called a special session of the Legislature for the purpose of passing Senate Bill 1 (the "Bill"),[4] which included Wisconsin's new product liability law, Wis. Stat. § 895.047 (which is almost verbatim § 2(b)).[5] The Wisconsin Legislature passed the Bill, Governor Walker signed it into law,[6] and the Bill became effective on February 1, 2011.[7]

Since Wis. Stat. § 895.047 was passed, there have been few cases interpreting or applying the provisions that relate to product defect. But certain points are clear. First, the Wisconsin legislature clearly intended to replace the consumer expectations test with the reasonable alternative design and risk-utility standards set forth in § 2(b). Second, as a corollary, many of the pre-2011 cases relied upon by the Plaintiffs in their various submissions, including in their MIL responses and portions of the Pretrial Order, are no longer valid and do not accurately describe Wisconsin law.

II. Wis. Stat. § 895.047 Applies to Plaintiffs' Strict Liability Design Defect Claim.

The Wisconsin product liability statute, Wis. Stat. § 895.047, provides as follows:

> (1) In an action for damages caused by a manufactured product based on a claim of strict liability, a manufacturer is liable to a claimant if the claimant establishes all of the following by a preponderance of the evidence:
>
> (1)(a) . . . A product is defective in design if the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption

[4] *See* NOA at Tab 12; Wis. Sen. Bill 1 (2011), NOA at Tab 13.

[5] For a comparison of the two provisions, please see Section II.C.i, *infra* at page 5.

[6] *See Governor Walker Signs Tort Reform Legislation* (Jan. 27, 2011), NOA at Tab 17.

[7] *See* Wis. Act 2 (2011), NOA at Tab 18.

> of a reasonable alternative design by the manufacturer and the omission of the alternative design renders the product not reasonably safe. . . .
>
> (1)(b) That the defective condition rendered the product unreasonably dangerous to persons or property.
>
> (1)(c) That the defective condition existed at the time the product left the control of the manufacturer.
>
> (1)(d) That the product reached the user or consumer without substantial change in the condition in which it was sold.
>
> (1)(e) That the defective condition was a cause of the claimant's damages.

A. Wisconsin Lacks Controlling Case Law Interpreting Wis. Stat. § 895.047, and, Thus, the Court Should Utilize Established Rules of Statutory Interpretation.

Bard's counsel has found no reported Wisconsin appellate court decision interpreting Wis. Stat. § 895.047(1). In the absence of controlling authority, Wisconsin courts turn first to the express language of the statute to interpret it. *See, e.g., State ex rel. Kalal v. Circuit Court for Dane Cty.*, 681 N.W.2d 110, 124 (Wis. 2004); *Strenke v. Hogner*, 694 N.W.2d 296, 301 (Wis. 2005). If the statute is ambiguous, courts turn to the legislative history and the common law meaning of the phrase in question, respectively. *See id.* Courts also examine statutes in a broader context, exploring the "context, subject matter, scope, and history to illustrate fully the legislature's objectives," including reference to extrinsic aids such as "materials pertaining to the passage of a statute, historical events that occurred at the time of enactment, and information generated after the statute's passage." *Seider v. O'Connell*, 612 N.W.2d 659, 671 (Wis. 2000).[8]

The express language of Wis. Stat. § 895.047(1)(a) demonstrates that Wisconsin has adopted the "reasonable alternative design" test set forth in § 2(b). Although the statute does not define the terms utilized in the statute, the language parrots § 2(b), which provides strong indications of the import of the provision. The legislative history of the

[8] Because this Court is applying Wisconsin law, it is "bound by decisions of [Wisconsin's] highest court" interpreting Wisconsin law. *Trishan Air, Inc. v. Fed. Ins. Co.*, 635 F.3d 422, 427 (9th Cir. 2011) (internal quotation marks and citation omitted). "In the absence of such a decision, a federal court must predict how the highest state court would decide the issue using intermediate appellate court decisions, decisions from other jurisdictions, statutes, treatises, and restatements as guidance." *Id.* (internal quotation marks and citation omitted).

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

statute, as well as other persuasive authorities (such as earlier Wisconsin opinions and restatement comments), further define the meaning of the statute.

B. The Legislative Intent of Wis. Stat. § 895.047 Was to Move Wisconsin Into the "Mainstream" by Eliminating the "Consumer Expectations" Test.

The legislative history of the Bill confirms Wisconsin's intent to eliminate the consumer expectations test as the sole test for design defect, and to adopt a reasonable alternative design test instead.

On January 11, 2011, the Joint Committee considering the Bill held a public hearing.[9] Brian Hagedorn, Chief Legal Counsel for Governor Walker, testified:

> The [Bill] also contains numerous reforms in the area of products liability including by ***adopting what's called the reasonable alternative design test instead of what Wisconsin has which is the consumer contemplation test***. That test has been rejected by nearly all states and most of them have some form of reasonable alternative design test.[10]

This intent was confirmed by Wisconsin Senator Rich Zipperer—one of the Bill's sponsors—during a floor debate on January 18, 2011:

> So what does the bill before us do? It addresses several areas in tort law where Wisconsin is the outlier and it brings us back into the mainstream.[11]

Thus, the intended effect of Wis. Stat. § 895.047 was to promote business interests in Wisconsin and to place "a larger burden on consumers to prove the defective condition of products."[12] This includes jettisoning the consumer expectations test in favor of a "reasonable alternative design" test to prove a design defect.

C. Wisconsin Authorities and Comments to the Restatement (Third) Confirm § 895.047(1)(a) Is a Rejection of the Consumer Expectations Test.

i. Wis. Stat. § 895.047(1)(a) Is a Codification of § 2(b), and a Rejection of the Consumer Expectations Test.

---

[9] *See* Wis. Sen. Record of Committee Proceedings, NOA at Tab 14.

[10] Wis. Sen. Bill 1 (2011): Public Hearing before Joint Committee on Judiciary, Ethics, Utilities, Commerce and Government, January 11, 2011 (testimony of Brian Hagedorn, Chief Legal Counsel to Gov. Scott Walker) (emphasis added), NOA Tab 15.

[11] Wis. Sen. Floor Session: Sen. Bill 1, January 18, 2011 (statement of Senator Rich Zipperer), NOA at Tab 16.

[12] Doyle Letter, NOA at Tab 11.

The language of Wis. Stat. § 895.047(1)(a) is taken nearly verbatim from §2(b):

§2(b) of the Restatement (Third):	**Wis. Stat. § 895.047(1)(a):**
"A product . . . is defective in design when the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design by the seller . . . and the omission of the alternative design renders the product not reasonably safe."	"A product is defective in design if the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design by the manufacturer and the omission of the alternative design renders the product not reasonably safe."

Prior to the enactment of Wis. Stat. § 895.047, the Wisconsin Supreme Court on three occasions considered but declined to adopt § 2(b); instead, favoring the continued application of the consumer expectation test under § 402A. *See Godoy*, 768 N.W.2d at 681–82; *Horst*, 769 N.W.2d at 536 (Gableman, J., concurring); *Green*, 629 N.W.2d at 736, 752.

In 2001, *Green* rejected § 2(b) because of concerns that it "increases the burden for injured consumers" by "requiring proof of the manufacturer's negligence" and "adding an additional—and considerable—element of proof to the negligence standard." *Id.* at 752–53. In her dissent, Justice Diane Sykes recognized that Wisconsin was in the "distinct minority" of jurisdictions that rely exclusively on a consumer expectations test, and "decisions relying exclusively on a consumer expectations test for determining liability in design defect cases have been roundly criticized." *Id.* at 766 (Sykes, J., dissenting).

After *Green*, the Wisconsin Legislature in 2005 attempted to legislatively adopt § 2(b), but the bill was vetoed. *See* Section I, *supra*. In 2009, in *Godoy*, the Wisconsin Supreme Court revisited the issue, but again refused to judicially adopt § 2(b). *Godoy*, 768 N.W.2d at 681–82. In a concurring opinion, Justice Prosser criticized the consumer expectations test, noting that "applying the consumer contemplation test to defective design claims runs the risk of labeling entire product lines defective without ever considering the utility the products create for society," and he advocated for the "Restatement (Third)'s risk-utility balancing approach." *Id.* at 696–97 (Prosser, J., concurring). But in a separate concurring opinion, Justice Bradley (the Justice who also

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

wrote the majority opinion) recognized that adoption of § 2(b) "would be a sea change in Wisconsin law," and it is the "role of the legislature to identify and enact policy initiatives." *Id.* at 689, 690 (Bradley, J. concurring).

Similarly, in *Horst*, Justice Gableman stated that Wisconsin had "stubbornly stuck with the anachronistic consumer contemplation test despite voluminous ongoing and unanswered criticism." 769 N.W.2d at 557 (Gableman, J., concurring). One problem with the consumer expectations test is "the practical reality that consumer/user expectations might be determined by a jury to be either unrealistically and unreasonably high or unacceptably low when compared with the optimum level of safety." *Id.* at 558–59. According to Justice Gableman, "[t]he Restatement (Third) helps avoid unreasonably high expectations with its negligence-style evaluation of the costs and benefits." *Id.* at 559.

It is against this background that the Wisconsin Legislature enacted Wis. Stat. § 895.047. Because the legislature "is presumed to act with full knowledge of existing case law when it enacts a statute," *Strenke*, 694 N.W.2d at 302, the Legislature is presumed to have known and intended that the adoption of language from § 2(b) would constitute the "sea change" in Wisconsin law articulated by Justice Bradley in *Godoy*, *see* 768 N.W.2d at 689 (Bradley, J., concurring), including rejection of the consumer expectations test and adoption of a reasonable alternative design test (with the attendant risk/benefit considerations). *See, e.g.*, *id.* at 696–97 (Prosser, J., concurring).

ii. The Restatement (Third) and Courts Applying it Reject the Consumer Expectations Test.

In the absence of controlling Wisconsin common law interpreting Wis. Stat. § 895.047(1)(a), this Court should look to other decisions and restatements for guidance. *See Trishan Air*, 635 F.3d at 427.

(a) Opinions in *Green*, *Godoy*, and *Horst* Provide Guidance for Interpreting Wis. Stat. § 895.047(1)(a).

Before Wis. Stat. § 895.047(1)(a) was enacted, Justices from the Wisconsin Supreme Court provided guidance regarding the meaning and import of § 2(b). In *Green*,

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

the majority recognized that § 2(b) "departs from the consumer-contemplation test set forth in the Restatement (Second) . . . and blurs the distinction between strict products liability claims and negligence claims." 629 N.W.2d at 751. Likewise, in his concurrence in *Godoy*, Justice Prosser recognized "the consumer contemplation test utilized by Restatement (Second) § 402A, makes little or no sense in the context of defective design claims," and adoption of "§ 2(b) removes the focus of the inquiry in defective design cases from the ordinary consumer's expectations and shifts it to asking whether the product's design was reasonable." 768 N.W.2d at 695–97 (Prosser, J., concurring). This inquiry requires a "risk-utility balancing approach [that] flows from the premise that risks must be foreseeable in order for the manufacturer to protect against them." *Id.* at 697. Finally, in *Horst*, Justice Gableman advocated for the "negligence-style evaluation of the costs and benefits" under § 2(b). 769 N.W.2d at 559 (Gableman, J., concurring).

Based on this history, Wisconsin clearly departed from the consumer expectations test when it adopted Wis. Stat. § 895.047, and replaced that test with a negligence-styled "reasonableness ('risk-utility balancing') test as the standard for judging the defectiveness of product designs." § 2, cmt. d (1998).

(b) The Comments to § 2(b) Provide Guidance for Interpreting Wis. Stat. § 895.047(1)(a).

The Comments to § 2(b) also provide important guidance in applying Wisconsin's version of § 2(b). In the dissenting and concurring opinions in *Green*, *Godoy*, and *Horst* that advocated for adoption of § 2(b), Justices Sykes, Prosser, and Gableman repeatedly relied on portions of those Comments. *See*, *e.g.*, *Godoy*, 768 N.W.2d at 696–99 (Prosser, J., concurring) (citing comments a, b, d, e, f, and l); *Horst*, 769 N.W.2d at 557, 559–60 (citing comments a and d); *Green*, 629 N.W.2d at 765–66 (citing comments a and d).

Comment d makes clear that "[s]ubsection [2](b) adopts a reasonableness ('risk-utility balancing') test as the standard for judging the defectiveness of product designs." § 2, cmt. d (1998). The test includes "whether the omission of the alternative design by the seller . . . rendered the product not reasonably safe." *Id.* Determining whether the

omission of an alternative design is reasonable "in most instances requires a comparison between an alternative design and the product design that caused the injury, undertaken from the viewpoint of a reasonable person. That approach is also used in administering the traditional reasonableness standard in negligence." *Id.* In other words, conformance to the "state of the art" is relevant to determine if a product is defective. *Id.* Additionally, although not dispositive, "[i]ndustry practice may also be relevant to whether the omission of an alternative design rendered the product not reasonably safe." *Id.*

Comment f provides this Court with a "broad range of factors [that] may be considered in determining whether an alternative design is reasonable and whether its omission renders a product not reasonably safe." § 2, cmt. f (1998). Those factors include: (1) "the magnitude and probability of the foreseeable risks of harm"; (2) "the instructions and warnings accompanying the product"; (3) "[t]he relative advantages and disadvantages of the product as designed and as it alternatively could have been designed"; (4) "the likely effects of the alternative design on production costs"; (5) "the effects of the alternative design on product longevity, maintenance, repair, and esthetics"; and (6) "the range of consumer choice among products are factors that may be taken into account."[13] *Id.* Comment f notes these "factors interact with one another." *Id.* "[E]vidence

[13] Bard recognizes Comment f identifies one factor as "the nature and strength of consumer expectations regarding the product, including expectations arising from product portrayal and marketing." § 2, cmt. f (1998). Additionally, Comment g states that while "consumer expectations do not play a determinative role in determining defectiveness . . . consumer expectations about product performance and the dangers attendant to product use affect how risks are perceived and relate to foreseeability and frequency of the risks of harm, both of which are relevant under Subsection (b)." Although Justice Sykes believed that "consumer expectations are relevant but not dispositive" under § 2(b), *Green*, 629 N.W.2d at 768 (Sykes, J., dissenting), Bard respectfully suggests that it is unclear, at best, whether the Wisconsin Supreme Court would adopt the consumer expectations portion of comment f, or any part of comment g to § 2(b). Notably, neither Justice Sykes in *Green*, nor Justice Prosser in *Godoy*, nor Justice Gableman in *Horst* cite to comment g. And given how clear (a) Justice Prosser was in *Godoy* that the consumer expectations test "makes little or no sense in the context of defective design claims," *Godoy*, 768 N.W.2d at 696, (b) the majority in *Green* acknowledged that § 2(b) "departs from the consumer-contemplation test," *Green*, 629 N.W.2d at 751, and (c) the legislative intent in enacting Wis. Stat. § 895.047(1)(a) was to "adopt[] what's called the reasonable alternative design test instead of what Wisconsin has which is the consumer contemplation test," testimony of Brian Hagedorn, *supra* Note 10, Bard suggests that the Wisconsin Supreme Court may reject the consumer expectations test altogether, even as a factor under the risk/benefit test. Indeed, in addressing this very issue, District Court Judge Rebecca Pallmeyer, who

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

of the magnitude and probability of foreseeable harm may be offset by evidence that the proposed alternative design would reduce the efficiency and the utility of the product." *Id.*

D. Wis. Stat. § 895.047(1)(b) Does Not Apply a Consumer Expectations Test.

Wisconsin's product liability statute also requires that a "defective condition render[] the product unreasonably dangerous" before a Plaintiff may recover. Wis. Stat. § 895.047(1)(b). The statute does not define "unreasonably dangerous" or identify what evidence is necessary to meet this standard. Nor has Bard's counsel located any Wisconsin appellate opinion interpreting this portion of the product liability statute.

An MDL court in Illinois, however, has applied § 895.047(1)(b). *See In re: Zimmer*, 218 F. Supp. 3d 700, 724–25 (N.D. Ill. 2016), *aff'd* 884 F.3d 746 (7th Cir. 2018). In *Zimmer*, on a motion for summary judgment, the Illinois District Court addressed whether the plaintiffs presented sufficient evidence that the product at issue was unreasonably dangerous. Although the court did not squarely answer that question (because the court ruled that the plaintiff could not establish the foundational requirement of a reasonable alternative design), it did express "concerns about Plaintiffs' ability to establish that the [product's] design is unreasonably dangerous" based on the opinions of the plaintiffs' two proffered experts. *Id.* at 725. The court noted that the first expert did "not offer an opinion about the absolute risk" of the product "and thus can also offer no opinion about whether such a risk makes the [product] unreasonably dangerous." *Id.* Regarding the second expert, the court expressed concern that he had not "conducted a risk-benefit analysis" and could not opine whether the product was "unsafe." *Id.*

The *Zimmer* analysis suggests that whether a product is "unreasonably dangerous" under Wis. Stat. § 895.047(1)(b) turns on a "risk-benefit analysis" and the "absolute risk" of the product, not on what an ordinary user or consumer may expect from the device. Indeed, the *Zimmer* court's analysis of Wis. Stat. § 895.047(1)(b) makes no mention of

---

was overseeing a Zimmer knee implant MDL, questioned whether a continued application of the consumer expectations test and Comment g "is an accurate statement of the law in Wisconsin." *In re: Zimmer Nexgen Knee Implant Prods. Liab. Litig.*, 218 F. Supp. 3d 700, 723 (N.D. Ill. 2016) (applying Wisconsin law), *aff'd* 884 F.3d 746 (7th Cir. 2018).

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

consumer expectations at all. Thus, the one court to address the statute has, in essence, utilized a risk-benefit approach to determine whether the product is unreasonably dangerous under Wis. Stat. § 895.047(1)(b).[14]

That "unreasonably dangerous" no longer contemplates a consumer expectations test—thus rendering pre-2011 Wisconsin opinions inapplicable on this point because they have been superseded by statute—is consistent with Wisconsin's intent to exorcise consumer expectations entirely from Wisconsin's law. *See* Section II.B, *supra*; Section II.C.ii.(b) & Note 13, *supra*.[15]

E. Wis. Stat. § 895.047(3)(b) Creates a Rebuttable Presumption of Non-Defectiveness.

Under Wisconsin's product liability statute, "[e]vidence that the product, at the time of sale, complied in material respects with relevant standards, conditions, or specifications adopted or approved by a federal or state law or agency shall create a rebuttable presumption that the product is not defective." Wis. Stat. § 895.047(3)(b). The plain language of the statute is broad, and not limited to federal or state "safety" standards or regulations. The Wisconsin pattern jury instruction does not limit the rule to safety standards. *See* Wis. JI-Civil 3260.1.[16] Nor does any controlling authority from a

[14] This is consistent with at least one other opinion from Iowa that found "unreasonably dangerous" to be pseudonymous with "not reasonably safe." *Ackerman v. Am. Cyanamid Co.*, 586 N.W.2d 208, 220 n.4 (Iowa 1998) ("Some of our later cases refer to the 'unreasonably dangerous' element as requiring proof that the product was not 'reasonably safe.'") (Ternus, J., concurring in part and dissenting in part).

[15] If consumer expectations has any role at all in Wisconsin's product liability law, it is as but a factor in determining product defectiveness. *See* § 2, cmt. g (1998). And the consumer or "user" of a product in the prescription medical device context is the physician who uses the device. *See Hall v. Boston Sci. Corp.*, No. 2:12-cv-08186, 2015 WL 874760, at *6 (S.D. W. Va. Feb. 27, 2015) (applying Wisconsin law); *see also, e.g.*, *Adams v. Synthes Spine Co.*, 298 F.3d 1114, 1117 (9th Cir. 2002) (applying Washington law) ("Under Washington law, the 'consumer' of a prescription-only medical device . . . is the physician, not the patient in whom it is installed . . . ."); *St. Clair v. Nellcor Puritan Bennett LLC*, No. CV-10-1275-PHX-LOA, 2011 WL 5331674, at *6–7 (D. Ariz. Nov. 7, 2011) (applying Arizona law) ("the consumers" in the consumer-expectations test for prescription medical devices are "the medical professionals who used the" device).

[16] The relevant part of the Wisconsin jury instruction reads: "There was evidence that at the time of sale, the product complied in material respects with relevant standards, conditions, or specifications adopted or approved by a federal or state law or agency. From this evidence, a rebuttable presumption arises that the product was not defective.

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

Wisconsin appellate court support grafting a "safety" limitation onto this rule. *See Winebarger v. Boston Sci. Corp.*, No. 5:15cv57-RLV, 2015 WL 5567678 (W.D.N.C. Sept. 21, 2015) (rejecting the plaintiffs' attempt to impute "safety" limitation into statute governing evidence of compliance with "any applicable government standard," as its plain meaning encompasses 510(k) clearance).

Indeed, the Western District of Wisconsin recently held "where a governmental agency issues certain regulations, requires compliance with those regulations, and then issues and reissues a certification based on a demonstration that those requirements are met, the presumption applies." *Kilty v. Weyerhaeuser Co.*, No. 16-CV-515-WMC, 2018 WL 2464470, at *3 (W.D. Wis. June 1, 2018) (discussing presumption based on compliance with National Institute of Occupational Safety and Health and U.S. Bureau of Mines regulations governing the performance and quality of respiratory equipment, but denying summary judgment when there was sufficient evidence for a jury to find the product was defective). Nothing in *Kilty* suggests that only safety regulations are entitled to the presumption of non-defectiveness under Wis. Stat. § 895.047(3)(b). *Id.*[17]

Although this Court previously ruled that "the presumption of non-defectiveness afforded by § 895.047(3)(b) is not applicable" because Bard provided no legal authority to

---

However, there is also evidence which may be believed by you that the product is defective. You must resolve this conflict. Unless you are satisfied by the greater weight of the credible evidence, to a reasonable certainty, that it is more probable than not that the product was defective, then in answering Question No. 1, you should find that the product was not defective." Wis. JI-Civil 3260.1 at 2.

[17] That the standards in *Kilty* may have been federal "safety" standards, and thus were sufficient to satisfy Wis. Stat. § 895.047(3)(b)'s requirement of "relevant standards" adopted or approved by a federal law or agency, does not mean that "safety" is a necessary condition under the statute. Nevertheless, as shown in Bard's prior briefing (*see* Docs. 5396, 7828, 9690), safety and efficacy do play an important role in FDA's decision-making in the 510(k) clearance process. *See also Medtronic Inc. v. Lohr*, 518 U.S. 470, 490–91 (1996) (noting that the MDA was enacted "to provide for the safety and effectiveness of medical devices intended for human use" and that the primary issue motivating the MDA's enactment was "the safety of those who use medical devices."); *Otero v. Zeltiq Aesthetics, Inc.*, No. CV 17-3994, 2018 WL 3012942 (C.D. Cal. June 11, 2018) ("Although *Medtronic* observed that obtaining Section 510(k) clearance is not as onerous as the "rigorous" PMA process, the Supreme Court did not find that the former has no bearing on a device's safety and effectiveness."). Indeed, this Court agreed that "[t]he SMDA did introduce safety and effectiveness considerations into 510(k) review," even if the standard for those considerations is comparative. Doc. 8872 at 12.

support that the presumption applies even if the government standard is not safety, (Doc. 12007 at 11, 12 n.4), respectfully, Bard submits that this question warrants more detailed briefing in light of the recent *Kilty* decision. At the time of the summary judgment briefing, which concluded in October 2017, Bard did not have the benefit of the *Kilty* opinion (decided June 1, 2018). *See Kilty*, 2018 WL 2464470, at *3. This case, in conjunction with the plain language of the statute, Wis. JI-Civil 3260.1, and the secondary authority *supra*, show that there is no safety limitation in Wis. Stat. § 895.047(3)(b), notwithstanding the contrary decisions by Judge Goodwin in West Virginia.[18]

Furthermore, it would be fundamentally unfair to permit Plaintiffs to argue that Bard is liable for negligence per se because of its alleged violations of "safety" statutes and regulations (the FDCA and its implementing regulations), but preclude Bard from defending the non-defectiveness of the G2X and Eclipse filters because these same statutes and regulations are not "safety" standards for purposes of § 895.047(3)(b). *See, e.g., Totsky v. Riteway Bus Serv., Inc.*, 607 N.W.2d 637, 644 (Wis. 2000) ("Negligence per se arises from the violation of a safety statute."); Wis. JI-Civil 1009. "[A]bsent a *safety* statute or an established private right of action, [the Supreme Court of Wisconsin] has never held that parties have an absolute right to admit evidence of violation of a civil statute to show a standard of care." *Grube v. Daun*, 570 N.W.2d 851, 855–56 (Wis. 1997) (emphasis added). Here, there is no private right of action to enforce the FDCA. *See* Docs. 8874 at 17; 10404 at 17. Therefore, Plaintiffs claim for negligence per se fails as a matter

[18] In fact, this is similar to the Georgia cases discussed in this Court's *Cisson* Order involving federal "safety" standards that were sufficient but not necessary to satisfy the government rules defense under Georgia law. *See* Doc. 9881 at 5 (discussing, e.g., *Doyle v. Volkswagenwerk Aktiengesellschaft*, 481 S.E.2d 518, 521 (Ga. 1997)). There too Judge Goodwin and the Fourth Circuit inappropriately imputed a "safety" limitation into the Georgia rule. The Georgia jury instruction even discussed "safety" standards when setting forth the rule. Notwithstanding this persuasive authority, this Court agreed that the controlling Georgia cases did not limit the rule to safety regulations. *See* Doc. 9881 at 5. Bard respectfully suggests that the result should be the same here, as the plain language of § 895.047(3)(b) is clear that the presumption applies to compliance with "relevant standards," not "safety" standards, and nothing in the *Kilty* case suggests otherwise. Whether Wisconsin's statutory presumption applies in this case, and whether the plaintiffs have overcome the presumption, should be a question of fact for the jury to resolve. *See* Wis. JI-Civil 3260.1 at 2 ("You [the jury] must resolve this conflict.").

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

of law unless the FDCA and its implementing regulations are considered "safety" statutes and regulations. *See Grube*, 570 N.W.2d at 855–56. Bard should not be precluded from having the jury resolve the presumption of non-defectiveness afforded by Wis. Stat. § 895.047(3)(b) based on these same "safety" statutes and regulations.

F. Wis. Stat. § 895.047(3)(d) Precludes Liability for Damage Caused by an "Inherent Characteristic" of the Product.

Wis. Stat. § 895.047(3)(d) provides the following defense in a product liability action:

> (d) The court shall dismiss the claimant's action under this section if the damage was caused by an inherent characteristic of the product that would be recognized by an ordinary person with ordinary knowledge common to the community that uses or consumes the product.

Neither Wisconsin's products liability statute nor Wisconsin appellate decisions interpreting it define what "inherent characteristic" means. But, the defense is similar to a pre-2011 common law defense recognized by the court in *Godoy*. 768 N.W.2d 674. That case involved design defect allegations concerning the presence of lead in white lead carbonate pigment. The court held that a "claim for defective design cannot be maintained where the presence of lead is the alleged defect in design, and its very presence is a characteristic of the product itself." *Id.* at 685; *see also id.* at 684 (comment h to § 402A "does not state that a defective condition can arise from harmful ingredients that ***are*** characteristic of the product" (emphasis in original)).[19] In this case involving an IVC filter, the alleged "damage" to Plaintiffs was caused by the risk of filter fracture, which is an "inherent characteristic" associated with all IVC filters. If the risk of fracture were removed from an IVC filter, it would "transform it into a different product," *Godoy*, 768 N.W.2d at 684, because all IVC filters carry the risk of fracture.

Wis. Stat. § 895.047(3)(d) also does not identify who is the "ordinary person with

[19] Because *Godoy* was decided before Wis. Stat. § 895.047(3)(d) was enacted, "it is not clear to what extent *Godoy* controls today." *Hall*, 2015 WL 874760, at *5. But because the defense in Wis. Stat. § 895.047(3)(d) is "similar to the one articulated by the *Godoy* court," and because the statute "does not indicate whether it replaces the common law or merely supplements it," a court should interpret the statute "in light of *Godoy*." *Id.*

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

ordinary knowledge common to the community that uses or consumes the product." But in the only court opinion that Bard's counsel could find that has applied this statutory defense, *Hall v. Boston Scientific*, in a prescription medical device case, the MDL judge considered the "ordinary person" to be the physician using the product, and not the patient. *See Hall*, 2015 WL 874760, at *6. While the parties in *Hall* "assume[d] that an 'ordinary' user for purposes of § 895.047 is the implanting physician," *id.* at *6 n.2, that assumption makes sense in light of the plain language of the statute, which references "the community that uses or consumes the product." Wis. Stat. § 895.047(3)(d). Patients are not a community that use IVC filters, but physicians are. Thus, it is the "ordinary" user of IVC filters—i.e., a physician who implants IVC filters—whose knowledge is relevant to the application of Wis. Stat. § 895.047(3)(d). *Cf., e.g., St. Clair*, 2011 WL 5331674, at *7 (in medical device case, "the ordinary consumer under the consumer expectation test is the physician who used the [product]"); *Soufflas v. Zimmer, Inc.*, 474 F. Supp.2d 737, 751 (E.D. Pa. 2007) ("the intended user" of medical device "is the prescribing physician").

III. Negligent Design Defect

To establish a claim of negligence, a plaintiff must prove the following elements:

(1) the existence of a duty of care on the part of the defendant,
(2) a breach of that duty of care,
(3) a causal connection between the defendant's breach of the duty of care and the plaintiff's injury, and
(4) actual loss or damage resulting from the injury.

Gritzner v. Michael R., 611 N.W.2d 906, 912 (Wis. 2000).

In the negligent design defect context, "manufacturers have a duty to 'exercise ordinary care in the design, construction, and manufacture' of their products." *Regent Ins. Co. v. Cincinnati Ins. Co.*, No. 14-C-1434, 2015 WL 7681254, at *3 (E.D. Wis. Nov. 24, 2015) (quoting Wis. JI-Civil 3240). The defendant manufacturer is held to the "'reasonable person' standard of customary methods of manufacture in a similar industry." *Morden v. Cont'l AG*, 611 N.W.2d 659, 675 (Wis. 2000). A manufacturer should conduct "all reasonable and adequate tests and inspections 'so as to guard against any defective condition which would render such product unsafe when used as it is

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

intended to be used.'" *Regent*, 2015 WL 7681254, at *3 (quoting Wis. JI-Civil 3240). Whether a product is negligently designed and unsafe "turns essentially on whether the seller could have come up with a less dangerous design." *Below v. Yokohama Tire Corp.*, No. 15-CV-529-WMC, 2017 WL 679153, at *3 (W.D. Wis. Feb. 21, 2017) (internal quotation marks and citation omitted). But proving that "better methods of manufacture exist does not conclusively prove that a defendant created the product with a lack of ordinary care"; instead, the plaintiff must "prove that the defendant selected the more dangerous route of manufacture knowing that it was unsafe." *Morden*, 611 N.W.2d at 675. This inquiry requires a risk/benefit analysis. *See Meyer v. Val-Lo-Will Farms, Inc.*, 111 N.W.2d 500, 503 (Wis. 1961) ("Conduct constitutes negligence if the risk of harm involved is of such magnitude as to outweigh what the law regards as the utility of the act or the manner in which it is done."); *see also Green*, 629 N.W.2d at 751 (citing *Meyer* and stating in a parenthetical that "negligence claims require a risk-benefit analysis").

Because manufacturers are held to the "reasonable person" standard of customary methods of manufacture in a similar industry, conformance or nonconformance with industry customs and the state of the art "provide[s] evidence to the jury about whether the defendant reasonably could have done something to prevent the harm." *Morden*, 611 N.W.2d at 675. Additionally, evidence of compliance with FDA regulations concerning medical devices—even in the context of a Class II medical device—is relevant to determine whether the manufacturer fulfilled its duty of care. *See Stevens v. Stryker Corp.*, No. 12-CV-63-bbc, 2013 WL 4758948 at *4 (W.D. Wis. Sept. 4, 2013) (allowing expert testimony concerning compliance with FDA regulations in Class II medical device case).

Regarding causation, that element "turns on whether the defendant's negligence was a substantial factor in producing the injury." *Morden*, 611 N.W.2d at 676 (internal quotation marks and citation omitted). "[C]ausation focuses on the nexus between the design or manufacture of the [product at issue] and [the plaintiff's] injuries." *Id.* Whether a sufficient "nexus" exists turns on whether the defendant's actions were a "cause-in-fact" and the "proximate cause" of the plaintiff's injuries. *Id.*

RESPECTFULLY SUBMITTED this 28th day of August, 2018.

s/ Richard B. North, Jr.
Richard B. North, Jr.
Georgia Bar No. 545599
Matthew B. Lerner
Georgia Bar No. 446986
NELSON MULLINS RILEY & SCARBOROUGH, LLP
Atlantic Station
201 17th Street, NW / Suite 1700
Atlanta, GA 30363
PH: (404) 322-6000
FX: (404) 322-6050
richard.north@nelsonmullins.com
matthew.lerner@nelsonmullins.com

James R. Condo (#005867)
SNELL & WILMER L.L.P.
One Arizona Center
400 E. Van Buren
Phoenix, AZ 85004-2204
PH: (602) 382-6000
jcondo@swlaw.com

Attorneys for Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc.

CERTIFICATE OF SERVICE

I hereby certify that on this 28th day of August 2018, the foregoing was electronically filed with the Clerk of Court using the CM/ECF system which will automatically send e-mail notification of such filing to all attorneys of record.

s/Richard B. North, Jr.
Richard B. North, Jr.

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000